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10/661,139	09/12/2003	Jagadish C. Sircar	AVANIR.111A	7736

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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 12/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/661,139	SIRCAR ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-41 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-41 are presented for examination.

Requirement for Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12 and 34-41, drawn to a pharmaceutical composition comprising a compound of genera I, II, III, IV, V, VI, VII or VIII or subgenera I(a), II(a), III(a), IV(a), V(a), VI(a), VII(a), VIII(a) and methods of preparing such compounds, classified in class 514, subclass 415, for example.

II. Claims 13-19, drawn to a method for treating or preventing an allergic reaction and/or inhibiting cytokines or leukocytes comprising the administration of a compound of genera I, II, III, IV, V, VI, VII or VIII, classified in class 514, subclass 415, for example.

III. Claims 20-22, drawn to a method for treating or preventing asthma comprising the administration of a compound of genera I, II, III, IV, V, VI, VII or VIII, classified in class 514, subclass 415, for example.

IV. Claims 23-33, drawn to a method for inhibiting cellular proliferation comprising the administration of a compound of genera I, II, III, IV, V, VI, VII or VIII, classified in class 514, subclass 415, for example.

The inventions are distinct, each from the other, for the following reasons:

Inventions I and Inventions II-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the composition of the phenylindole compound(s) may also be used in a materially different process of using such compounds. In particular, such a composition may be used for the treatment of allergic reactions; asthma; tumorigenesis; cancer; inflammatory disorders; or circulatory disorders.

Inventions II through IV are patentably distinct. Inventions are patentably distinct if it can be shown that they have different modes of operation, different functions, or different effects and different resultant endpoints (See MPEP § 806.04, MPEP § 808.01). In the instant case, it is noted that the ultimate therapeutic objective of, for example, Invention II (i.e., treating or preventing an allergic reaction in a subject) is distinct from the therapeutic objective of, for example, Invention IV (i.e., inhibiting cellular proliferation as associated with, for example, cancer, in a subject), of which each is distinct from the therapeutic objective of Invention III (i.e., treating or preventing asthma in a subject).

Inventions II through IV are held to be patentably distinct because the treatment of any one of Inventions II through IV would not necessarily result in the treatment of the other invention. The patient populations in which each method would be practiced are distinctly different (e.g., patients requiring the treatment of an allergic reaction versus patients requiring inhibition of abnormal cellular proliferation as associated with malignant cancer), such that the treatment of one patient population would not necessarily suggest, anticipate or render obvious the treatment of the other patient population. While there may be incidental overlap in the groups of patients experiencing, for example, allergic reaction and those experiencing, for example, abnormal cellular proliferation, the therapeutic objectives, endpoints and steps required

to treat such conditions are vastly different and do not reasonably suggest, anticipate or render obvious the treatment of the other.

Furthermore, the dosage amounts or frequency and route of administration necessary to effect the treatment of patients with, for example, allergic reaction, would necessarily be independent and distinct from that required for the treatment of patients with, for example, abnormal cellular proliferation, due to the differences in etiology of such a condition and the activity of the claimed agent(s) in treating such a condition. Moreover, one skilled in the art could practice the invention of any one or more of II, III or IV without practicing the invention of any one of the other inventions. Thus, Inventions II through IV are properly considered patentably distinct from one another.

Because these inventions are distinct for the reasons given above and the search required for any one of Groups I through IV is not required for any one of the other groups, the inventions are held to be distinct and restriction for examination purposes as indicated is proper.

Further Requirement for Election

Election of any one of groups I-IV requires an additional election of a compound and/or an additional agent to be administered concomitant with the elected compound, depending upon the elected group. The additional elections are explained below.

If Group I is elected:

Claims 1-12 are generic to a plurality of disclosed patentably distinct species comprising phenylindole compounds of the genera I, I(a), II, II(a), II(b), III, IV, V, VI, VII or VIII.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Election of the species of compound and additional agent will be made in accordance with the following groups:

(i) Compounds as set forth in claims 1-12: (a) compounds of genera I; (b) compounds of genera Ia; (c) compounds of genera II; (d) compounds of genera II(a); (e) compounds of genera IIb; (f) compounds of genera III; (g) compounds of genera IV; (g) compounds of genera V; (i) compounds of genera VI; (j) compounds of genera VII; or (k) compounds of genera VIII.

Applicant is further required under 35 U.S.C. 121 to elect a **single** disclosed species of compound (i.e., one single compound of genera I should Applicant elect (a) or one single compound of genera I(a) should Applicant elect (b), etc.) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement and a listing of all claims readable thereon, including any claims subsequently added. A structural depiction of the elected species of compound and a description of the identity of each chemical moiety contained within such an elected species of compound (i.e., R, R1, R2, L, M, etc.) is also required. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should Applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

If Group II or Group III is elected:

This application contains claims directed to the following patentably distinct species of the claimed invention: (i) compounds of genera I, II, III, IV, V, VI, VII or VIII and (ii) an additional agent to be administered concomitant with a compound of genera I-VIII.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 13 or 20-21 are generic to compounds of genera I, II, III, IV, V, VI, VII and VIII and claims 15 or 22 are generic to additional agents.

Election of the species of compound and additional agent will be made in accordance with the following groups:

(i) Compounds as set forth in claims 13 or 20-21: (a) compounds of genera I; (b) compounds of genera II; (c) compounds of genera III; (d) compounds of genera IV; (e) compounds of genera V; (f) compounds of genera VI; (g) compounds of genera VII; or (h) compounds of genera VIII.

Applicant is further required under 35 U.S.C. 121 to elect a **single** disclosed species of compound (i.e., one single compound of genera I should Applicant elect (a) or one single compound of genera II should Applicant elect (b), etc.) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

(ii) Additional agents as set forth in claims 15 or 22: (a) short acting beta-2-adrenergic agonist; (b) long acting beta-2-adrenergic agonist; (c) antihistamine; (d) phosphodiesterase

inhibitor; (e) anticholinergic agent; (f) corticosteroid; (g) inflammatory mediator release inhibitor; or (h) leukotriene receptor antagonist.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement and a listing of all claims readable thereon, including any claims subsequently added. A structural depiction of the elected species of compound and a description of the identity of each chemical moiety contained within such an elected species of compound (i.e., R, R1, R2, L, M, etc.) is also required. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

If Group IV is elected:

This application contains claims directed to the following patentably distinct species of the claimed invention: (i) compounds of genera I, II, III, IV, V, VI, VII or VIII and (ii) an additional agent or therapy to be administered concomitant with a compound of genera I-VIII.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 23 is generic to compounds of genera I, II, III, IV, V, VI, VII and VIII and claims 25-26 and 32-33 are generic to additional agents or therapies.

Election of the species of compound and additional agent will be made in accordance with the following groups:

(i) Compounds as set forth in claim 23: (a) compounds of genera I; (b) compounds of genera II; (c) compounds of genera III; (d) compounds of genera IV; (e) compounds of genera V; (f) compounds of genera VI; (g) compounds of genera VII; or (h) compounds of genera VIII.

Applicant is further required under 35 U.S.C. 121 to elect a **single** disclosed species of compound (i.e., one single compound of genera I should Applicant elect (a) or one single compound of genera II should Applicant elect (b), etc.) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

(ii) Additional agents or therapies as set forth in claims 25-26 and 31-33: (a) antifungals; (b) antivirals; (c) antibiotics; (d) anti-inflammatories; (e) anticancer agents; (f) alkylating agent; (g) antimetabolite; (h) DNA cutter; (i) topoisomerase I poison; (j) topoisomerase II poison; (k) DNA binder; (l) spindle poison; (m) anti-cancer therapy; (n) radiation; (o) immunotherapy; (p) gene therapy; or (q) surgery.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement and a listing of all claims readable thereon, including any claims subsequently added. A structural depiction of the elected species of compound and a description of the identity of each chemical moiety contained within such an elected species of compound (i.e., R, R1, R2, L, M, etc.) is also required. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Connie Tong at Knobbe, Martens, Olson & Bear, L.L.P. on Monday, December 05, 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The Examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. 1.116; amendments submitted after allowance are governed by 37 C.F.R. 1.312.

I n the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper

restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicants are advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the Examiner withdraws the restriction requirement before the patent issues. See MPEP §804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-6:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

December 5, 2005

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